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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,054

03/22/2006

Anthony Robert Milnes Coates

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

11/12/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/534,054

**Applicant(s)**COATES, ANTHONY ROBERT  
MILNES**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-35 and 37-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-35, 37-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's Response to Office Action, received 1 August 2008, is acknowledged. Claims 31, 34, 35, 39, 40, 42, 43, 51 and 53 have been amended. Claims 29, 30, and 36 have been canceled.
2. Claims 31-35 and 37-53 are pending and under consideration.

### **Rejections Moot or Withdrawn**

3. The objection to Figure 4 is withdrawn in light of the replacement figure.
4. The objection to Figure 5 is withdrawn in light of the replacement figure.
5. The objection to Figure 6 is withdrawn in light of the replacement figure.
6. The objection to Figure 7 is withdrawn in light of the replacement figure.
7. The objection to Figure 8 is withdrawn in light of the replacement figure.
8. The objection to Figure 9 is withdrawn in light of the replacement figure.
9. The objection to claim 34 is withdrawn in light of the replacement figure.
10. The rejection of claims 39-50 under 35 U.S.C. 112, second paragraph, as being indefinite for "a", "the", is withdrawn in light of the amendment of the claims.
11. The rejection of claims 40-48 under 35 U.S.C. 112, second paragraph, as being indefinite for "assisting or augmenting" is withdrawn in light of the amendment of the claims.
12. The rejection of claim 42 under 35 U.S.C. 112, second paragraph, as being indefinite for "form", is withdrawn in light of the amendment of the claim.
13. The rejection of claim 36 under 35 U.S.C. 112, second paragraph, as being indefinite for sequences, is moot in light of the cancellation of the claim.

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14. The rejection of claim 36 under 35 U.S.C. 112, first paragraph, scope of enablement for any/all fragments of said heat shock proteins providing pain relief, is moot in light of the cancellation of the claim.

15. The rejection of claims 29, 30, and 36 under 35 U.S.C. 112, first paragraph, scope of enablement for relieving pain by administration of polynucleotides encoding a heat shock polypeptide, is moot in light of the cancellation of the claims.

### **Rejections Maintained**

16. The rejection of claims 31-34 and 38 under 35 U.S.C. 112, second paragraph, as being indefinite for "derived", is maintained.

Applicant argues that one of skill in the art would understand, based upon the specification and common vernacular used in the art, that derived is regularly used to indicate the origin of a particular biological material.

The examiner has considered applicant's argument, but does not find it persuasive for the reasoning put forth in the original rejection explanation. While "derived" may encompass the indication of origin of said material, it remains unclear what form or forms the material encompasses.

17. The rejection of claims 34, 35, 37, and 38 under 35 U.S.C. 112, second paragraph, as being indefinite for sequences, is maintained in part.

Applicant argues that the amendment of the claims to recite "of SEQ ID NOs: 1, 2, and 3" obviates the rejection.

The examiner has considered applicant's argument in light of the claim amendments, and finds it persuasive in part. The sequence identity of the references sequences is now

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definite, but the second indefiniteness remains, i.e., whether the claimed sequences consist of or are subsequences of the designated SEQ ID NOs.

18. The rejection of claims 34, 35, 37, and 38 under 35 U.S.C. 112, first paragraph, scope of enablement for any/all fragments of said heat shock proteins providing pain relief, is maintained.

Applicant argues that: (1) as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement is satisfied; and (2) the applicant need not describe all actual embodiments.

The examiner has considered applicant's argument, but does not find it persuasive. As put forth in the original rejection, the specification utilizes only whole cpn 60.1, cpn 60.2 or cpn 10. The specification does not direct a person of skill in the art to any particular part (subsequence) which is the critical component to be retained in order to achieve the claimed results. The specification only teaches that the whole material produces the required results. Thus, any subsequence, or sequence other than 100% identical to cpn 60.1, cpn 60.2 or cpn 10 is not supported by the teachings of the instant specification.

19. The rejection of claims 31-35 and 37-53 under 35 U.S.C. 112, first paragraph, scope of enablement for relieving pain by administration of polynucleotides encoding a heat shock polypeptide, is maintained for reasons of record.

Applicant argues that the specification provides ample guidance in combination with the common technical knowledge in the art to enable one of ordinary skill in the art to make and use the presently claimed invention.

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The examiner has considered applicant's argument, but does not find it persuasive for the reasoning put forth in the original rejection explanation. While the specification teaches whole cpn 60.1, cpn 60.2 or cpn 10 polypeptide can achieve the required results, the specification provides no evidence that the nucleotides encoding said whole polypeptides can replace the whole polypeptides and retain all of their pain relief characteristics as claimed.

### **Claim Rejections - 35 USC § 112**

20. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is dependent from cancelled claim 36.

### **Conclusion**

22. Claims 31-35 and 37-53 are finally rejected.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a)

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will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

27 November 2008